



PCT

10/516941

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

	(1 61 7 11 10 10 1					
Applicant's or agent's file reference PF-030005-WO	FOR FURTHER AC	rion	See Form PCT/IPEA/416			
International application No.	International filing date	(day/month/year)	Priority date (day/month/year)			
PCT/JP2003/008400	02 July 2003 (02.07.2003)	16 July 2002 (16.07.2002)			
International Patent Classification (IPC) or a A61K 47/34, 47/10, 47/14, 9/06		IPC				
Applicant	SSP CO.	, LTD.				
This report is the international prelication Authority under Article 35 and transport in the second se	iminary examination repo smitted to the applicant a	rt, established by this ccording to Article 3	s International Preliminary Examining 6.			
2. This REPORT consists of a total of	f sheets,	including this cover	sheet.			
This report is also accompanied by						
a. (sent to the applicant an	d to the International Bur	eau) a total of	sheets, as follows:			
and/or sheets co	sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).					
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.						
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).						
4. This report contains indications re	lating to the following iter	ns:				
Box No. I Basis of the	report					
Box No. II Priority						
Box No. III Non-establis	hment of opinion with re	gard to novelty, inver	ntive step and industrial applicability			
Box No. IV Lack of unit	y of invention					
Box No. V Reasoned st	atement under Article 35(I explanations supporting	2) with regard to nov	elty, inventive step or industrial applicability;			
Box No. VI Certain doct	-	gadii giatoiiidii				
	cts in the international ap	plication				
Box No. VII Certain defects in the international application						
Date of submission of the demand		Date of completion	of this report			
26 January 2004 (26.0)1.2004)	2	7 May 2004 (27.05.2004)			
Name and mailing address of the IPEA/JF		Authorized officer				
Facsimile No.		Telephone No.				

Translation



International application No.

PCT/JP2003/008400

Ç.

Box No.	I	Basis of the report
		It to the language, this report is based on the international application in the language in which it was filed, unless addicated under this item.
	This which	report is based on translations from the original language into the following language, this language of a translation furnished for the purpose of:
		international search (under Rules 12.3 and 23.1(b))
		publication of the international application (under Rule 12.4)
		international preliminary examination (under Rules 55.2 and/or 55.3)
		·
furnis	hed to re not	d to the elements of the international application, this report is based on (replacement sheets which have been to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" tannexed to this report):
		nternational application as originally filed/furnished
		escription:
	page	
	page:	
	•	
	the c	laims:
	page	
	page	
	page	
	page	s* received by this Authority on
	the d	rawings:
	page	
	page	
	page	s* received by this Authority on
	a seq	uence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3.	The	amendments have resulted in the cancellation of:
	\Box	the description, pages
	H	the claims, Nos.
	님	
	H	the drawings, sheets/figs
l	H	the sequence listing (specify):
	لــا	any table(s) related to sequence listing (specify):
4.	made	report has been established as if (some of) the amendments annexed to this report and listed below had not been e, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box e 70.2(c)). the description, pages
	Ħ	the claims, Nos.
	H	the drawings, sheets/figs
	H	the sequence listing (specify):
	님	
}		any table(s) related to sequence listing (specify):
* If iten	n 4 a <u>p</u>	oplies, some or all of those sheets may be marked "superseded."

International application No.

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Tho questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrial applicable have not been examined in respect of: the entire international application. olaims Nos.				PC1/JP03/08400
the entire international application. claims Nos	Box No.	III Non-establishment of opin	nion with regard to novelty, inventive step an	d industrial applicability
claims Nos	The que applicab	stions whether the claimed invent le have not been examined in resp	tion appears to be novel, to involve an inventive	e step (to be non obvious), or to be industrial
the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): The subject matter of claims of		the entire international applicati	ion.	
the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): The subject matter of claims of coordance with PCT article 34(4) (a) (i) and Rule 67.1(iv). the description, claims or drawings (Indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. by the description that no meaningful opinion could be formed. no international search report has been established for said claims Nos. on international search report has been established for said claims Nos. he nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: the written form has not been furnished does not comply with the standard the computer readable form has not been furnished does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.	\boxtimes	claims Nos.	9	
relate to the following subject matter which does not require an international preliminary examination (specify): The subject matter of claim 9 relates to methods for treatment of the human body by therapy, which do not require an international preliminary examination by the International Preliminary Examining Authority in ecordance with PCT article 34(4) (a) (i) and Rule 67.1(iv). the description, claims or drawings (indicate particular elements below) or said claims Nos	becaus	se:		
The subject matter of claim 9 relates to methods for treatment of the human body by therapy, which do not require an international preliminary examination by the International Preliminary Examining Authority in coordance with PCT article 34(4) (a) (i) and Rule 67.1(iv). the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so unclear that no meaningful opinion could be formed. no international search report has been established for said claims Nos. 9 the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: the written form has not been furnished does not comply with the standard the computer readable form has not been furnished does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.	\boxtimes	the said international applicatio relate to the following subject n	n, or the said claims Nos. natter which does not require an international pr	9
the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed. In ointernational search report has been established for said claims Nos 9 The nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: The written form has not been furnished does not comply with the standard the computer readable form has not been furnished does not comply with the standard the computer readable form has not been furnished does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.		he subject matter of claim 9 ire an international prelimin	relates to methods for treatment of the	human hade be the street 1: 1 1
by the description that no meaningful opinion could be formed. no international search report has been established for said claims Nos		the description, claims or drawing are so unclear that no meaningfu	ngs <i>(indicate particular elements below)</i> or said al opinion could be formed <i>(specify)</i> :	claims Nos.
no international search report has been established for said claims Nos		the claims, or said claims Nos by the description that no meaning	ngful opinion could be formed.	are so inadequately supported
the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: the written form				
the written form has not been furnished does not comply with the standard the computer readable form has not been furnished does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.	□ .	the nucleotide and/or amino acid	sequence listing does not comply with the stand	•
the computer readable form has not been furnished does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.				
does not comply with the standard the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.		the computer randal - S		
the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.		and comparer readable form		
		he tables related to the nucleotide he technical requirements provide	and/or amino acid sequence listing if in compa	uter readable form only, do not comply with ructions.



International application No.
PCT/JP03/08400

Reasoned statement citations and explana	under Article 35(2) with regations supporting such staten	ard to novelty, inventive step or industr nent	ial applicability;
(N)	Claims		YES
	Claims	1-8	NO
re step (IS)	Claims		YES
	Claims	1-8	NO NO
al applicability (IA)	Claims	1-8	YES
	Claims		NO NO
,	(N) e step (IS)	(N) Claims Claims e step (IS) Claims Claims Claims Claims	Claims

2. Citations and explanations (Rule 70.7)

Document 1: JP, 10-182450, A (SSP Co., Ltd.), 7 July, 1998 (07.07.98), pages 5 and 6, entire document, Example 4 (Family: none)

Document 2: JP, 7-285861, A (Dott Research Laboratory), 31 October, 1995 (31.10.95), entire document, Examples 4-10 (Family: none)

(Documents 1 and 2 are both cited in the ISR.)

(1)

Document 1 (pages 5 and 6, Example 4) describes liquid medicine compositions for external application that are well absorbed transdermally, wherein the said compositions contain diclofenac or their salts as active ingredients, and also, propylene glycol, propylene glycol mono oleate, and polyoxyethylene lauryl ether (these three are found to correspond to components (a), (b) and (c) defined in claim 1 of the present application respectively) at a weight ratio of 20:8:0.5.

Accordingly, the subject matters of claims 1-7 do not appear to be novel or to involve an inventive step in view of document 1.

Preparing oil ointments or oil cream agents by mixing the above-mentioned compositions for external application with base oil agents as required, based on the descriptions of document 1 (page 5, [0025]), would not be difficult for a person skilled in the art.

So, the subject matter of claim 8 does not appear to involve an inventive step in view of document 1.



International application No.

PCT/JP03/08400

ertain published documents (R	ule 70.10)				
Application No. Patent No.	Publication da		Filing date (day/month/year)	Priority date (valid (day/month/ye	l claim)
JP 2003-93152 A	02.04.200	3	26.09.2001		
[E, X]					
,					
Von-written disclosures (Rule			a directorure	Date of written disclosure	e Osure
Non-written disclosures (Rule Kind of non-written di		Date of non-writte (day/month/	n disclosure (year)	Date of written disclosure referring to non-written disclosure (day/month/year)	e osure
		Date of non-writte (day/month/	n disclosure (year)	referring to non-written discle	e osure
		Date of non-writte (day/month)	n disclosure (year)	referring to non-written discle	e osure
		Date of non-writte (day/month/	n disclosure (year)	referring to non-written discle	e osure
		(day/month/	n disclosure (year)	referring to non-written discle	e osure
	isclosure I	(day/month/	n disclosure (year)	referring to non-written discle	e osure
	isclosure I	(day/month/	n disclosure (year)	referring to non-written discle	e osure
	isclosure I	(day/month/	n disclosure (year)	referring to non-written discle	e osure
	isclosure I	(day/month/	n disclosure (year)	referring to non-written discle	e osure



International application No.

PCT/JP03/08400

INTERNATIONAL PRODUCTION AND ADDRESS OF THE PRODUCTION AND ADDRESS				
Box No. VIII Certain observations on the international application				
The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully apported by the description, are made: The defining expression, "comparatively highly lipophilic," contained in claim 5, which refers to an inclear degree of lipophilicity, makes the subject matter of the said claim unclear.				
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International application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient. Continuation of: V.2

Document 2 (Examples 4-10) describes cream medicine compositions for external application that are well absorbed transdermally, wherein the said compositions contain 3,5-bis(acetoxyacetylamino)-4chlorobenzonitrile as an active ingredient, and also, propylene glycol, sorbitan monostearate, and polyoxyethylene lauryl ether (these three are found to correspond to components (a), (b) and (c) defined in claim 1 of the present application respectively) at a weight ratio of 6.0-7.0:3.0-4.5:2.0.

Accordingly, the subject matters of claims 1-6 and 8 do not appear to be novel or to involve an inventive step in view of document 2.

Creating liquid preparations by mixing agents of the above-mentioned compositions with commonly used supplementary ingredients such as an appropriate solvent additionally as required would be merely a change of dosage forms that a person skilled in the art could make as required.

So, the subject matter of claim 7 does not appear to involve an inventive step in view of document 2.

特 許 協 力 条 約

10/51694A

PCT

特許性に関する国際予備報告 (特許協力条約第二章)

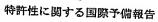
(法第12条、法施行規則第56条) [PCT36条及びPCT規則70]

REC'D	17	MUL	2004
WIPO			PCT

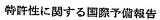
の書類記号 PF-030005-WO	一学後の手続きにつ 	かいては、様式PCT/ 〕	【PEA/416を 参	ほする	こと。
国際出願番号 PCT/JP03/08400	国際出願日 (日.月.年) 02	. 07. 2003	優先日 (日.月.年) 16.	07.	2002
国際特許分類 (IPC) Int. Cl' A61K47/34, A61K47/	10, A61K47/14, A	61K9/06, A61K9/08, A61	K9/12, A61K9/70		
出願人(氏名又は名称)	ス製薬株式会社				
1. この報告書は、PCT35条に基づき 法施行規則第57条(PCT36条)の)規定に従い送付す	機関で作成された国際予る。	ゲ備審査報告である。		
2. この国際予備審査報告は、この表紙を	_	<u>7</u> ペーシ	^ど からなる。		•
3. この報告には次の附属物件も添付される	ıている。 ページであ	る。			
補正されて、この報告の基礎 囲及び/又は図面の用紙 (F	をされた及び/又 CT規則70.16及で	はこの国際予備審査機関 ブ実施細則第607号参	引が認めた訂正を含む 照)	明細書、	、請求の範
第 I 欄 4 . 及び補充欄に示し 国際予備審査機関が認定した	√たように、出願時 :差替え用紙	における国際出願の開示	の範囲を超えた補正	を含む	ものとこの
b 電子媒体は全部で 配列表に関する補充欄に示すよ ブルを含む。(実施細則第80	うに、コンピュー 2号参照)	夕読み取り可能な形式に	(電子媒体の利 よる配列表又は配列	重類、数 表に関連	を示す)。 車するテー
4. この国際予備審査報告は、次の内容を	 含む。				
□ 第IV欄 発明の単一性のク	又は産業上の利用で で如 に規定する新規性 とび説明 は	J能性についての国際予√ 、進歩性又は産業上の利		見解、そ	それを裏付
				-	
国際予備審査の請求部を受理した日 26.01.2004		国際予備審査報告を作 2.7	成した日		
名称及びあて先 日本国特許庁 (IPEA/JP) 郵便番号100-8915 東京都千代田区段が関三丁目4番	3 号	特許庁審査官(権限の 大久保元浩	ある職員)	4 C	8828

電話番号 03-3581-1101 内線

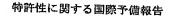
3452



第1欄 報告の基礎		
1. この国際予備審査報告は、	下記に示す場合を除	くほか、国際出願の言語を基礎とした。
この報告は、	――― 語による翻訳	文を基礎とした。
それは、次の目的で提入 PCT規則12.3及7	ゴされた翻訳文の官語 げ23.1(b)にいう国際間	うである。
□ PCT規則12.4にV	いう国際公朋	
	ょ は55.3にいう国際予備	! Cifer −ak-
2. この報告は下記の出願書類	を基礎とした。 (法第	66条(PCT14条)の規定に基づく命令に応答するために提出さ この報告に添付していない。
た差替え用紙は、この報告にお	いて「田願時」とし、	この報告に添付していない。)
X 出願時の国際出願書類		
DE 6mets		
」明細 魯 第	•	
第	ページ、 ページ*、	出願時に提出されたもの
第	~	付けで国際予備審査機関が受理したも
		一 付けで国際予備審査機関が受理したも
請求の範囲 第		
第	項、 項*、	出願時に提出されたもの
第		PCT19条の規定に基づき補正されたもの
第	項*、	付けで国際予備審査機関が受理したもの
図面		付けで国際予備審査機関が受理したもの
第	ページ/図、	111 per release to a second
第	ページ/図*、	
第	ページ/図*、	一一一一一一一付けで国際予備審査機関が受理したもの
□ 配列表又は関連するテー		付けで国際予備審査機関が受理したもの
配列表に関する補充	ノル 爛を参照 かっとし	
	11 6 5 11 3 C C 0	
. □ 補正により 下記の事物	****	
・ 補正により、下記の書類	が削除された。	
□ 明細書	第	
□ 請求の範囲	第	ページ 項
図面	第	ページ/図
□ 配列表(具体的に配する) 配列表に関連するテー	以すること)	
	ノル(具体的に記載	すること)
この報告は、補充欄に示し		
こうの教育は、補充欄に示し	たように、この報告	に添付されかつ以下に示した補正が出願時における開示の範囲を越 されなかったものとして作品した。(2007)2007
たくこれのにものと呼吸のられ	るので、その補正が	に忝付されかつ以下に示した補正が出願時における開示の範囲を越 されなかったものとして作成した。 (PCT規則70.2(c))
□ 別和督 第	ĵ	20 20
開求の範囲 第		
図面 第		
□ 配列表に関連するテー	すること) ブル (目体的):======	
	- ・・ (メイヤーソル)に同じ収す	男のこと)
		}
1. に咳当する場合、その用紙に	"Superseded" Lan	7 44 7 7 1 14 1 4
	hornoned CHE'	へつれることがある。
PCT/IPEA/400 (m		
	a 2000)	



			四际山嶼街	F PUT/JP03/	38400
	第Ⅲ柳 新規性、進歩性又は産業上の	利用可能性についての」	 見解の不作成		
	1. 次に関して、当該請求の範囲に記 審査しない。			(上の利用可能性につき、	次の理由により
	国際出願全体				
	X 請求の範囲9				
	理由: X この国際出願又は請求の範囲 次の事項を内容としている(具体	9 的に記載 す ること)。		は、国際予備審査をする、	ことを要しない
	請求の範囲9は治療 PCT第34条(4) り、この国際予備審査 である。		Vbし、し、神田田で	7 1 /	I Production of
	□ 明細書、請求の範囲若しくは図面 記載が、不明確であるため、見解を	(次に示す部分) 又は請: :示すことができない (₃	求の範囲 具体的に記載すること	<u>-) .</u>	
	.v.				
			•		
	全部の請求の範囲又は請求の範囲 裏付けを欠くため、見解を示すこと	ができない		が、明細書	による十分な
X		9.)		
	」 ヌクレオチド又はアミノ酸の配列表が	は 実施細則の似居事の	******	際調査報告が作成されて	いない。
	ヌクレオチド又はアミノ酸の配列表がのガイドライン)に定める基準を、₹	大の点で満たしていない。	(塩基配列又はアミ ₎	ノ酸配列を含む明細む等	の作成のため
	書面による配列表が コンピュータ読み取り可能な形式に		提出されていない 所定の基準を満れ 提出されていない 所定の基準を満れ	こしていない。 い こしていない。	
	コンピュータ読み取り可能な形式によ Cの2に定める技術的な要件を、次の	るヌクレオチド又はアミ 点で満たしていない。	ミノ酸の配列表に関連	ばするテーブルが、実施約	四則の附属書
	□ 提出されていない。 □ 所定の技術的な要件を満たして	•			
	詳細については補充欄を参照すること。	b			
M-1	tnom (re-				



. 見解		
新規性(N)	請求の範囲 請求の範囲 1-8	
進歩性 (IS)	請求の範囲 請求の範囲 <u>1-8</u>	
産業上の利用可能性 (IA)	請求の範囲1-8 請求の範囲	

・文献 1 : JP 10-182450 A (エスエス製薬株式会社) 1998.07.07 文献全体、p. 5-6実施例4 (ファミリーなし)

JP 7-285861 A(有限会社ドット)1995.10.31 ・文献 2 : 文献全体、実施例4 -10(ファミリーなし)

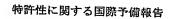
(文献1,2はいずれも国際調査報告で引用された文献である)

(1)

文献 1 のp. 5-6実施例 4 には、薬効成分としてジクロフェナク又はその塩を含み かつ、プロピレングリコール、モノオレイン酸プロピレングリコール及びポリオキシエチレンラウリルエーテル(三者はこの順に、本願請求の範囲1に規定される成分(a)、成分(b)及び成分(c)に該当するものと認める)を、重量比で20:8

よって、請求の範囲1-7はいずれも、文献1により新規性及び進歩性を有さな

また、例えば文献 1 p. 5【0025】の記載に基づき、上記組成の外用組成物に適宜油 性基剤を配合せしめて油性軟膏剤又は油性クリーム剤を調製することは、当業者にとり格別の困難性を要することではない。 よって、請求の範囲8は、文献1により進歩性を有さない。



第VI欄	ある種の引用文献
100	マン ショウマンソーカコ 大田人

1. ある種の公表された文書 (PCT規則70.10)

> 出願番号 特許番号

公知日 (日.月.年)

出顧日 __(日.月.年) 優先日(有効な優先権の主張)

____(日.月.年)

JP 2003-93152 A 02. 04. 2003 [E, X]

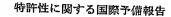
26.09.2001

書面による開示以外の開示 (PCT規則70.9) 2.

書面による開示以外の開示の種類

整面による開示以外の開示の日付 (日. 月. 年)

む面による開示以外の開示に言及している



第VII-欄 国際出願に対する意見

請求の範囲、明細書及び図面の明瞭性又は請求の範囲の明細書による十分な裏付についての意見を次に示す。

請求の範囲5中に規定されている、「<u>比較的</u>親油性の高い」なる親油性に関する程 度不明瞭な表現は、同請求の範囲の発明を不明確にするものである。

様式PCT/IPEA/409 (第Ⅷ欄) (2004年1月)

ý.

特許性に関する国際予備報告

国際出願番号 PCT/JP03/08:400

補充櫚

いずれかの欄の大きさが足りない場合

第 V 欄の続き

(2)

また、上記組成の剤に対し、適切な溶媒等の慣用の補助成分を適宜追加配合して液 状製剤とすることは、当業者が必要に応じ適宜なし得る剤型の変更に過ぎない。 よって、請求の範囲7は、文献2により進歩性を有さない。

様式PCT/IPEA/409 (補充欄) (2004年1月)